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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,401

11/21/2005

Hiroshi Tsuchita

Q88294

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09/12/2008

SUGHRUE-265550

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EXAMINER

TSAY, MARSHA M

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

09/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,401	Applicant(s) TSUCHITA ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2008, has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn

Claims 2, 8-15, 17, 23 are canceled. Claims 1, 3-7, 16, 18-22 are currently under examination.

Priority: The request for priority to JAPAN 2002-350200, filed December 2, 2002, is acknowledged.

Objection and Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-7, 16, 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 16, and their dependent claims recite “whey protein component.” It is unclear what is meant by “component”, or what is the component of the whey protein. Further clarification is requested.

Claims 3, 7, 18, and 22 recite a decomposition product of whey protein. It is unclear what is meant by or what exactly is a "decomposition product" (i.e., a denatured protein, a degraded protein, etc.). Further clarification is requested.

Claims 5-6 recite the composition according to claim 1, which "comprises". The claims are dependent on claim 1, which uses closed claim language "consists of" to recite a composition which consists of leucine, isoleucine, valine, glutamine, and a whey protein. Claims 5-6 are indefinite because the use of open language “comprises” allows for anticipation of additional components; however, the claims are dependent on a claim that uses closed claim language “consists of” and therefore restricts additional components. Appropriate correction is requested.

Claims 20-21 are rejected for the same reasons as noted for claims 5-6 except claims 20-21 are dependent on claim 16.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantman (US 4687782; IDS; previously cited). The use of open claim language “comprising” allows for anticipation by additional components. Since claim 16 recites a method which comprises

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administering a composition consisting of leucine, isoleucine, etc., the claim can be broadly and reasonably interpreted to mean that additional compositions and/o components can also be administered along with said composition already recited in claim 16. Brantman teaches a composition consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein, soy protein, lactalbumin (col. 7 lines 30-50), adapted for use with water as a diet supplement for facilitating the adaptation of skeletal muscle and liver to a program of strenuous exercise. Brantman further teaches a method of supplementing the diet of an athlete by having the athlete drink a solution consisting essentially of leucine, isoleucine, valine, glutamine, and a whey protein, and having the athlete drink the solution (col. 6 lines 42-53; claim 16, 18-19, 22). In col. 4 lines 45-50, Brantman teaches numerical ranges for the amino acids used in the composition: leucine (20-45 parts), isoleucine (15-40 parts), valine (15-40 parts), glutamine (10-30 parts), carnitine (0.3-2.0 parts), wherein the relative proportions of the amino acids are preferably within 20% of the recited ranges (col. 5 lines 20-25; claims 20-21).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantman (US 4687782; IDS; previously cited). Brantman discloses a composition consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein, soy protein, lactalbumin (col. 7 lines 30-50), adapted for use with water as a diet supplement for facilitating

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the adaptation of skeletal muscle and liver to a program of strenuous exercise. Brantman further discloses a method of supplementing the diet of an athlete by having the athlete drink a solution consisting essentially of leucine, isoleucine, valine, glutamine, and a whey protein, and having the athlete drink the solution (col. 6 lines 42-53). In col. 4 lines 45-50, Brantman discloses numerical ranges for the amino acids used in the composition: leucine (20-45 parts), isoleucine (15-40 parts), valine (15-40 parts), glutamine (10-30 parts), carnitine (0.3-2.0 parts), wherein the relative proportions of the amino acids are preferably within 20% of the recited ranges (col. 5 lines 20-25). Brantman does not specifically teach a composition consisting of leucine, isoleucine, valine, glutamine, and a whey protein.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Brantman and formulate a composition consisting of isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein (claim 1) and administer said composition to an athlete (claim 16). One of ordinary skill would be motivated to administer said composition to an athlete and expect it to be successful in improving fatigue during exercise because Brantman teaches a composition consisting essentially of the branched amino acids, i.e. isoleucine, leucine, leucine, valine, glutamine, and a whey protein, which can be administered to promote muscle adaptation to strenuous exercise in a person.

In their remarks received January 7, 2008, Applicants assert the composition taught by Brantman consists essentially of carnitine, leucine, isoleucine, valine, glutamine, valine, and water. Applicants assert that the composition taught by Brantman contains carnitine as an

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essential ingredient. Applicants' arguments have been fully considered but they are not persuasive.

Brantman discloses that BAA (branched amino acids) are known to stimulate protein synthesis in muscles (col. 1 lines 60-65). The BAAs include leucine, isoleucine, valine (col. 1 line 64). However, glutamine is included with the BAAs because it is a known fuel for the kidney and intestines (col. 2 lines 57-58) and encourages protein synthesis in the liver (col. 3 lines 49-52). Brantman further discloses that one of the functions of BAAs in exercising muscle is, in effect, to remove lactate from muscle (col. 2 lines 61-63). Build-up of lactate in muscle is associated with muscle fatigue, and is considered to be undesirable (col. 2 lines 66-68 to col. 3 lines 1-15).

As previously noted, the composition of Brantman consists essentially of 0.025 g carnitine, 0.5 g glutamine, 0.625 isoleucine, 0.85 g leucine, 0.625 valine, and 2.5 g whey protein (col. 8 lines 5-18). Out of all the amino acids present in the Brantman composition, the amount of carnitine present (0.025 g) is the least compared with the BAAs, i.e. 0.5 g glutamine, 0.625 isoleucine, 0.85 g leucine, 0.625 valine, and 2.5 g whey protein. Therefore, it would be reasonable for one of ordinary skill to recognize that even if carnitine is disclosed as an ingredient in the composition of Brantman, it does not appear that its absence would interfere with the basic and novel characteristics of the claimed invention, i.e. which is to improve muscle fatigue and/or promote muscle adaptation to strenuous exercise.

Brantman has disclosed that the BAAs function to remove lactate from muscle, which would therefore reduce and/or prevent muscle fatigue. As disclosed by Brantman, it appears that carnitine helps to minimize the effects of ammonia that is generated during catabolism of amino

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acids, i.e. which occurs during strenuous exercise (col. 3 lines 64-68). However, one of ordinary skill would recognize that a composition consisting of glutamine, isoleucine, leucine, valine, and whey protein alone is sufficient to provide therapeutic benefit, i.e. providing the branched amino acids that are necessary for removing lactate from muscle (i.e., reduce/prevent muscle fatigue), and stimulating protein synthesis in skeletal muscle and in liver (col. 2 lines 61-68, col. 3 lines 20-35, col. 4 lines 15-20).

For these reasons, the Brantman reference is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

September 10, 2008